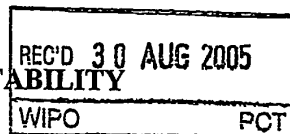


PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 718455	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/AU2004/000530	International filing date (day/month/year) 23 April 2004	Priority date (day/month/year) 23 April 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 17/68		
Applicant JAMES, Dugal Simon Stewart		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 7 sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 22 February 2005	Date of completion of the report 15 August 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer SUE THOMAS Telephone No. (02) 6283 2454

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000530

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1, 4-12 as originally filed/furnished

pages* 2, 3, 3a received by this Authority on 22 February 2005 with the letter of 22 February 2005

pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* 13-16 received by this Authority on 22 February 2005 with the letter of 22 February 2005

pages* received by this Authority on with the letter of

☒ the drawings:

pages 1-9 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000530

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
 - ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
 - ☐ complied with.
 - ☒ not complied with for the following reasons:
 1. Claims 1-5 and 15 relate to a fixation device and method for fixing a first member in a position relative to a second member, the fixation device including a shaft having a head and longitudinal axis, an external screw thread on the head, a first screw portion rotatable about the axis, an internal screw thread on the first screw portion configured to engage the external screw thread on the head, and a second screw portion rotatable about the axis independently of the first screw portion, wherein the first and second each have an external screw thread in a direction opposite to the external thread on the head, and configured to engage a bore formed in the first and second members. It is considered that the internal screw thread on the first screw portion configured to engage the external screw thread on the head comprises a first "special technical feature".
 2. Claims 6-14 relate to a fixation device for fixing a first member in a position relative to a second member, the fixation device including a shaft having a longitudinal axis and an externally threaded portion, a head on the shaft, a first screw portion rotatable about the axis, a second screw portion having an internal thread corresponding to the shaft thread and rotatable about the axis independently of the first screw portion, and a lock nut having an internal thread corresponding with the shaft thread and configured to maintain the position of the second screw portion on the shaft when the fixation device is assembled, wherein the first and second screw portions each have an external screw thread configured to engage a bore formed in the first and second members. It is considered that the lock nut configured to maintain the position of the second screw portion on the shaft comprises a second special technical feature.

Continued on extra sheet

4. Consequently, this report has been established in respect of the following parts of the international application:
 - ☒ all parts.
 - ☐ the parts relating to claims Nos.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000530

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. IV

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is a fixation device for fixing a first member in a position relative to a second member including a shaft having a head and a longitudinal axis, a first screw portion rotatable about the axis, a second screw portion rotatable about the axis independently of the first screw portion, wherein the first and second each have an external screw thread. However this concept is not novel in the light of US 5827285 A (BRAMLET). Therefore these claims lack unity a posteriori.

Since the common concept was searched and little additional examination effort is required to examine the second invention, this report is based on both inventions.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000530

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-15	YES
	Claims	NO
Inventive step (IS)	Claims 1-15	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-15	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 US 5827285

D2 US 4858601

D3 US 4640271

Novelty (N) Claims 1-15

The invention of amended claims 1 to 5 and 15 is a fixation device and method for fixing a first member in a position relative to a second member, the fixation device including a shaft having a head and longitudinal axis, an external screw thread on the head, a first screw portion rotatable about the axis, an internal screw thread on the first screw portion configured to engage the external screw thread on the head, and a second screw portion rotatable about the axis independently of the first screw portion, wherein the first and second each have an external screw thread in a direction opposite to the external thread on the head, and configured to engage a bore formed in the first and second members.

The invention of amended claims 6 to 14 is a fixation device for fixing a first member in a position relative to a second member, the fixation device including a shaft having a longitudinal axis and an externally threaded portion, a head on the shaft, a first screw portion rotatable about the axis, a second screw portion having an internal thread corresponding to the shaft thread and rotatable about the axis independently of the first screw portion, and a lock nut having an internal thread corresponding with the shaft thread and configured to maintain the position of the second screw portion on the shaft when the fixation device is assembled, wherein the first and second screw portions each have an external screw thread configured to engage a bore formed in the first and second members.

None of the cited documents disclose all of the features of each of the independent claims. The closest art of D1 discloses a fixation device for fixing a first member in a position relative to a second member including a shaft having a head and a longitudinal axis, a first screw portion rotatable about the axis, a second screw portion rotatable about the axis independently of the first screw portion, wherein the first and second each have an external screw thread, but fails to disclose either an internal screw thread on the first screw portion configured to engage the external screw thread on the head or a lock nut configured to maintain the position of the second screw portion on the shaft. Therefore all of the claims are novel.

Inventive Step (IS) Claims 1-15

The claimed inventions are not obvious in the light of any of the cited documents or disclosed in any obvious combination of them. It is also considered the inventions would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V

Industrial Applicability (IA) Claims 1-15

The amended claims are related to products capable of commercial application.

- (b) an external screw thread on the head;
- (c) a first screw portion rotatable about the axis;
- (d) an internal screw thread on the first screw portion configured to engage the external screw thread on the head, to facilitate assembly of the fixation device by screwing the first screw portion over the head; and
- (e) a second screw portion rotatable about the axis independently of the first screw portion;

wherein the first and second screw portions each have an external screw thread in a direction opposite to the external thread on the head, and configured to engage a bore formed in the first and second members thereby fixing the relative position of the members.

The external screw thread of the head may have a leading end and a trailing end such that the trailing end terminates in a flat end so as to substantially preclude engagement with a threaded member. The internal thread of the first screw portion configured to engage the external thread of the head preferably also has a leading end and a trailing end such that the trailing end terminates in a flat end so as to substantially preclude engagement with a threaded member. In such arrangement, when the first screw portion has been threaded over and past the external thread on the head, the threads do not easily re-engage, preventing the assembled screw from inadvertently being disassembled.

The fixation device may also include a lock nut having an internal thread corresponding with the shaft thread. Such lock nut is configured to maintain the position of the second screw portion on the shaft. The second screw portion may be integral with the shaft or attached to the shaft by threaded engagement, welding, glue or otherwise.

In another aspect of the present invention, there is provided a fixation device for fixing a first member in a position relative to a second member, the fixation device including:

- (a) a shaft having a longitudinal axis and an externally threaded portion;
- (b) a head on the shaft;
- (c) a first screw portion rotatable about the axis;

(d) a second screw portion having an internal thread corresponding to the shaft thread and rotatable about the axis independently of the first screw portion; and

(d) a lock nut having an internal thread corresponding with the shaft thread
5 and configured to maintain the position of the second screw portion on the shaft when the fixation device is assembled;

wherein the first and second screw portions each have an external screw thread configured to engage a bore formed in the first and second members thereby fixing the relative position of the members.

10 In one embodiment, the first screw portion is a collar screw and assembly of the fixation device includes passing the shaft through the collar screw prior to threadedly engaging the lock nut and the second screw portion on the shaft. In another embodiment, the first screw portion is a collar screw with an opening along its length for receiving a length of the shaft. Part of the
15 fixation device can then be assembled by fitting the first screw portion over the shaft.

In another form, the fixation device includes an external screw thread on the head which is in a direction opposite to the external thread on the first and second screw portions. The first screw portion further includes an internal screw
20 thread which engages the external thread on the head. In such arrangement, part of the fixation device is assembled by screwing the first screw portion over the head. The external screw thread on the head may have a leading end and a trailing end with the trailing end terminating in a flat end. This substantially precludes engagement with another threaded member. Similarly, the internal
25 thread on the first screw portion may also have a leading end and a trailing end with the trailing end terminating in a flat end, also substantially precluding engagement with another threaded member.

In some embodiments of the invention, the shaft may be flexible. In other embodiments, the shaft is rigid. Preferably, the first and second members are
30 bone. In some embodiments a retaining screw may be used to engage the head when the fixation device is in a bore, thereby retaining the device therein.

3a

According to another aspect of the invention, there is provided a method of fixing a first member in a position relative to a second member, the method including the steps of:

- 5 (a) assembling a fixation device; the fixation device having:
- (i) a shaft with a head and a longitudinal axis;
 - (ii) an external screw thread on the head;
 - (iii) a first screw portion rotatable about the axis;
 - (iv) an internal screw thread on the first screw portion configured to
10 engage the external screw thread on the head;
 - (v) a second screw portion rotatable about the axis independently of the first screw portion; and
 - (vi) an external screw thread on the first and second portions in a direction opposite to the external thread on the head, which is adapted to
15 engage a bore in the first and second members;
- wherein assembly of the fixation device includes screwing the first screw portion over the head;
- (b) forming a bore in the first and second members;
 - (c) introducing the assembled fixation device into the bore,
 - 20 (d) operating the fixation device in such a way that one of the first or second screw portions rotates relative to the threaded bore thereby engaging and positioning the first member relative to the second member; and
 - (e) locking the fixation device in position.

25

Brief description of the drawings

The invention will now be described in greater detail with reference to the
30 embodiments illustrated in the accompanying drawings. It is to be understood that the particularity of the accompanying drawings does not supersede the generality of the preceding description of the invention.

Figure 1a illustrates in cross section, a fixation device being inserted into a threaded bore in accordance with an embodiment of the invention.

Claims

1. A fixation device for fixing a first member in a position relative to a second member, the fixation device including:
 - 5 (a) a shaft having a head and a longitudinal axis;
 - (b) an external screw thread on the head;
 - (c) a first screw portion rotatable about the axis;
 - (d) an internal screw thread on the first screw portion configured to engage the external screw thread on the head, to facilitate assembly of the fixation
 - 10 device by screwing the first screw portion over the head; and
 - (e) a second screw portion rotatable about the axis independently of the first screw portion;

wherein the first and second screw portions each have an external screw thread in a direction opposite to the external thread on the head, and configured

 - 15 to engage a bore formed in the first and second members thereby fixing the relative position of the members.
-
2. A fixation device according to claim 1 further including a lock nut having an internal thread corresponding with the shaft thread, and configured to
 - 20 maintain the position of the second screw portion on the shaft.
-
3. A fixation device according to any one of the preceding claims wherein the external screw thread on the head has a leading end and a trailing end and the trailing end terminates in a flat end to substantially preclude engagement
 - 25 with a threaded member.
-
4. A fixation device according to any one of the preceding claims wherein the internal thread on the first screw portion which is configured to engage the external thread on the head has a leading end and a trailing end, and the
 - 30 trailing end terminates in a flat end to substantially preclude engagement with a threaded member.
-
5. A fixation device according to any one of the preceding claims wherein the second screw portion is integral with the shaft.

6. A fixation device for fixing a first member in a position relative to a second member, the fixation device including:
- (a) a shaft having a longitudinal axis and an externally threaded portion;
 - 5 (b) a head on the shaft;
 - (c) a first screw portion rotatable about the axis;
 - (d) a second screw portion having an internal thread corresponding to the shaft thread and rotatable about the axis independently of the first screw portion; and
 - 10 (d) a lock nut having an internal thread corresponding with the shaft thread and configured to maintain the position of the second screw portion on the shaft when the fixation device is assembled;
- wherein the first and second screw portions each have an external screw thread configured to engage a bore formed in the first and second members
- 15 thereby fixing the relative position of the members.
7. A fixation device according to claim 6 wherein the first screw portion is a collar screw and assembly of the fixation device includes passing the shaft through the collar screw prior to threadedly engaging the lock nut and the
- 20 second screw portion on the shaft.
8. A fixation device according to claim 6 wherein the first screw portion is a collar screw with an opening along its length for receiving a length of the shaft and assembly of the fixation device includes fitting the first screw portion over
- 25 the shaft.
9. A fixation device according to claim 6 wherein the head includes an external screw thread in a direction opposite to the external thread on the first and second screw portions, and the first screw portion further includes an
- 30 internal screw thread to facilitate assembly of the fixation device by screwing the first screw portion over the head.

10. A fixation device according to claim 9 wherein the external screw thread on the head has a leading end and a trailing end and the trailing end terminates in a flat end to substantially preclude engagement with a threaded member.
- 5 11. A fixation device according to claim 9 or claim 10 wherein the internal thread on the first screw portion, configured to engage the external thread on the head, has a leading end and a trailing end, and the trailing end terminates in a flat end to substantially preclude engagement with a threaded member.
- 10 12. A fixation device according to any one of the preceding claims wherein the shaft is flexible.
13. A fixation device according to any one of the preceding claims wherein the first and second members are bone.
- 15 14. A fixation device according to any one of the preceding claims further including a retaining screw configured to engage the head, thereby retaining the fixation device within the threaded bore.
- 20 15. A method of fixing a first member in a position relative to a second member, the method including the steps of:
- (a) assembling a fixation device, the fixation device having:
- (i) a shaft with a head and a longitudinal axis;
- (ii) an external screw thread on the head;
- 25 (iii) a first screw portion rotatable about the axis;
- (iv) an internal screw thread on the first screw portion configured to engage the external screw thread on the head;
- (v) a second screw portion rotatable about the axis independently of the first screw portion; and
- 30 (vi) an external screw thread on the first and second portions in a direction opposite to the direction of the external thread on the head and adapted to engage a bore in the first and second members;
- wherein assembly of the fixation device includes screwing the first screw portion over the head;

- (b) forming a bore in the first and second members;
- (c) introducing the assembled fixation device into the bore;
- (d) operating the fixation device in such a way that one of the first or second screw portions rotates relative to the threaded bore thereby engaging and
- 5 positioning the first member relative to the second member; and
- (e) locking the fixation device in position.

ABSTRACT

A fixation device for fixing a first member in a position relative to a second member has a shaft with a head and a longitudinal axis. The head has an external screw thread in a first direction. A first screw portion rotatable about the axis has an internal screw thread configured to engage the external screw thread on the head, thereby facilitating assembly of the fixation device by screwing the first portion over the head. A second screw portion is rotatable about the axis independently of the first screw portion. Each of the first and second screw portions has an external screw thread in a second thread direction and is configured to engage a bore formed in the first and second members. The fixation device is particularly useful in joining broken bones.